Statement of U.S. Smokeless Tobacco Company

Before the

House Committee on Energy and Commerce

Subcommittee on Commerce, Trade and Consumer Protection

"Can Tobacco Cure Smoking? A Review of Tobacco Harm Reduction"

June 3, 2003

U.S. Smokeless Tobacco Company ("USSTC") welcomes the opportunity to participate in this hearing regarding tobacco harm reduction. This issue is of immense importance to the 50 million adult tobacco consumers in the United States, to the public health community, to medical practitioners and to tobacco manufacturers.

For decades, the public health community in the United States has asserted that cigarette smoking is the most deadly epidemic of modern times. For almost as long, the message of the public health community to cigarette smokers has been monolithic: stop all use of tobacco. Over the past several years, however, an increasing number of public health advocates have voiced doubts about what some have called the "quit or die" approach to smoking cessation.

Rather than rely entirely on programs intended to achieve total cessation of tobacco use, this segment of the public health community is urging that a more pragmatic goal be adopted – that of tobacco "harm reduction." One method of achieving tobacco harm reduction, according to a growing number of researchers, is to encourage those cigarette smokers who do not quit and do not use medicinal nicotine products to switch completely to smokeless tobacco products. This strategy, however, is complicated by the fact that the vast majority of adult cigarette smokers in the United States – despite the generally accepted scientific view to the contrary – believe that cigarette smoking and smokeless tobacco use involve the same risk of adverse health effects.

The issue of tobacco harm reduction and the potential role of smokeless tobacco products in that effort is at a crossroads. The debate is no longer about whether smokeless tobacco is considered by the scientific community to be a significantly reduced risk alternative compared to cigarette smoking. The question now is whether that information should be communicated to adult cigarette smokers or whether it should be suppressed.

Set forth below is a brief description of USSTC and its smokeless tobacco products, followed by a review of some of the more significant issues relating to smokeless tobacco in the context of tobacco harm reduction.

I. USSTC

USSTC is the leading U.S. producer and marketer of moist smokeless tobacco or moist snuff. Copenhagen and Skoal -- two of USSTC's brands -- are America's best-selling moist snuff products. Two other brands -- Rooster and Red Seal -- were introduced within the last five years, and hold established positions in the marketplace. A new pouch product -- Revel -- has been test marketed. USSTC maintains manufacturing and processing facilities in Franklin Park, Illinois; Hopkinsville, Kentucky; and Nashville, Tennessee.

In 1997, USSTC was the only smokeless tobacco company to support the proposed tobacco resolution. When the proposal failed to pass the Congress, USSTC became the only smokeless tobacco company to enter into the Smokeless Tobacco Master Settlement Agreement ("STMSA") with Attorneys General of various states and U.S. territories. Pursuant to the STMSA, USSTC is providing up to $100 million (plus an inflation adjustment), over a 10-year period, to the American Legacy Foundation for programs to reduce youth usage of tobacco and

combat youth substance abuse, and for enforcement purposes.[1] Moreover, USSTC agreed to limitations on its advertising and marketing efforts, even though this put USSTC at a competitive disadvantage with other smokeless tobacco manufacturers.[2]

As these facts and the remainder of this statement will make clear, USSTC is truly a "distinctly different" tobacco company. Annexed as Attachment A to this statement are copies of excerpts from UST Inc.'s (USSTC's parent company) annual reports for 2000, 2001 and 2002 that discuss the ways in which USSTC is a "distinctly different" tobacco company.

II. Smokeless Tobacco in the Context of Tobacco Harm Reduction

A. Introduction

Since the Surgeon General's Report in 1964[3], there has been substantial public health discussion about the potential health effects of tobacco use. Various public health organizations have identified the risks of cigarette smoking as including cancer (*e.g.*, lung, oral cavity, esophagus, larynx, pancreas, bladder, kidney), chronic obstructive pulmonary disease,

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[1] Youth usage of smokeless tobacco, as reported in surveys conducted by various federal government agencies and by the University of Michigan, has declined substantially in recent years. For example, in 2001 the authors of the report on the University of Michigan's Monitoring the Future national survey noted that "[t]he use of smokeless tobacco by teens has been decreasing gradually from recent peak levels in the mid-'90s, and the overall declines have been substantial." Johnston LD, O'Malley PM, Bachman JG. (2001) *Monitoring the Future national results on adolescent drug use: Overview of key findings 2000*. (NIH Publication No. 01-4923). Bethesda, MD: National Institute of Drug Abuse, at p. 34. More recently, these same authors reaffirmed their earlier findings, noting that the overall declines in teen use of smokeless tobacco have been "substantial" and that "teen use of smokeless tobacco is down by about one-half from the peak levels reached in the mid-1990s." Johnston LD, O'Malley PM, Bachman JG. (2003). *Monitoring the Future national results on adolescent drug use: Overview of key findings, 2002.* (NIH Publication No. 03-5374). Bethesda, MD: National Institute on Drug Abuse, at p. 34.

[2] These restrictions include, among other things, eliminating outdoor advertising of smokeless tobacco products, such as billboards and signs in arenas, stadiums, shopping malls, video-game arcades, and on public transit. In addition, USSTC voluntarily limited itself to one brand-name sponsorship in any 12-month period, and agreed to discontinue distribution to the public of non-tobacco merchandise, such as caps and T-shirts, bearing the brand name, logo, or trademark of any smokeless tobacco product.

[3] U.S. Department of Health, Education and Welfare. *Smoking and Health. Report of the Advisory Committee to the Surgeon General of the Public Health Service*. 1964.

myocardial infarction, and stroke.[4] The Centers for Disease Control and Prevention ("CDC") estimates that cigarette smoking caused approximately 442,000 premature deaths in the United States in 1999.[5] The Surgeon General has indicated that the ideal way to avoid such health risks is to abstain from cigarette smoking.[6] Nonetheless, 47 to 50 million adults in the U.S. continue to smoke cigarettes. This number represents approximately 25 percent of all U.S. adults.[7]

The Surgeon General reached a judgment in 1986 that use of smokeless tobacco products "can cause cancer."[8] Federally-mandated rotating warnings on smokeless tobacco product packaging and advertising state:

> WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER
>
> WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS
>
> WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES.[9]

Numerous methods have been suggested by public health advocates for achieving tobacco harm reduction, including urging cigarette smokers to smoke fewer cigarettes, developing "less hazardous" cigarettes and creating alternative sources of nicotine, such as

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[4] Stratton K, Sherry P, Wallace R, Bondurant S (eds.). *Clearing the smoke. Assessing the science base for tobacco harm reduction. Institute of Medicine*. National Academy Press, Washington, D.C., 2001, at pp. 367-68.

[5] Centers for Disease Control and Prevention. Annual Smoking-Attributable Mortality, Years of Potential Life Lost, and Economic Costs — United States, 1995–1999. *MMWR* 2002; **51**: 300-303.

[6] U.S. Department of Health & Human Services, *Preventing Tobacco Use Among Young People: A Report of the Surgeon General* (1994)*; see also Smoking As A Health Hazard*, American College of Cardiology Position Statement, available at http://www.acc.org/clinical/position/72565.pdf.

[7] The National Center For Chronic Disease Prevention and Health Promotion estimates that 47 million adults in the United States smoke cigarettes. *Targeting Tobacco Use: The Nation's Leading Cause of Death*, Tobacco Information and Prevention Source (2001). The U.S. Department of Health and Human Services estimates that more than 57 million Americans currently smoke cigarettes. *Preventing Death and Disease From Tobacco Use*, Fact Sheet (Jan. 8, 2001). Other reports suggest that the number of smokers in the United States is between 46.5 and 50 million. *Cigarette Smoking Among Adults - United States, 1999, MMWR Highlight*s (Oct. 12, 2001) Vol. 50, No. 40; *Treating Tobacco Use and Dependence*, U.S. Public Health Service, Fact Sheet (June 2000).

[8] U.S. Department of Health & Human Services, *The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General* (1986).

[9] Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401-4408.

nicotine inhalers. A growing number of tobacco harm reduction proponents, however, are arguing for an additional method for achieving their goal. Based on the generally accepted view in the scientific community that smokeless tobacco use involves significantly less risk of adverse health effects than cigarette smoking, they would encourage those cigarette smokers who do not quit and do not use medicinal nicotine products to switch completely to smokeless tobacco products.

B. The IOM Report

A logical starting point for discussion of smokeless tobacco in the context of tobacco harm reduction is the 600 page report issued in 2001 by the Institute of Medicine ("IOM") entitled: *Clearing the Smoke. Assessing the Science Base for Tobacco Harm Reduction* ("IOM Report"). The IOM was established in 1970 by the National Academy of Sciences to examine policy matters pertaining to public health, and acts under the Academy's congressional charter to be an advisor to the federal government and to assess issues relating to medical care, research and education. The IOM tobacco harm reduction project was undertaken at the request of, and was supported by, the U.S. Food and Drug Administration. The IOM Report explains the need for a tobacco harm reduction strategy as follows:

> Despite overwhelming evidence and widespread recognition that tobacco use poses a serious risk to health, some tobacco users cannot or will not quit. For those addicted tobacco users who do not quit, reducing the health risks of tobacco products themselves may be a sensible response. This is why many public health leaders believe that what has come to be called "harm reduction" must be included as a subsidiary component of a comprehensive public health policy toward tobacco.[10]

Tobacco "harm reduction" is defined in the IOM Report as follows:

[10] Stratton K, et al. (2001) at p. 201.

> *For the purposes of this report, a product is harm-reducing if it lowers total tobacco-related mortality and morbidity even though use of that product may involve continued exposure to tobacco related toxicants*. Many different policy strategies may contribute to harm reduction. However, this report focuses on tobacco products that may be less harmful or on pharmaceutical preparations that may be used alone or concomitantly with decreased use of conventional tobacco. (Original emphasis). [11]

It is clear from this definition of "harm reduction" that, in the view of the IOM, it is not necessary to demonstrate that a product is "safe" or "harmless" in order for that product to play a role in tobacco harm reduction.

The IOM Report had the following to say with respect to smokeless tobacco products:

> Smokeless tobacco products are associated with oral cavity cancers, and a dose-response relationship exists. However, the overall risk is lower than for cigarette smoking, and some products such as Swedish snus may have no increased risk. It may be considered that such products could be used as a PREP [Potential Reduced-Exposure Product] for persons addicted to nicotine, but these products must undergo testing as PREPs using the guidelines and research agenda contained herein.[12]

There has been criticism of the IOM Report's recommendation that all products proposed for use in the context of a tobacco harm reduction strategy require substantial and elaborate scientific testing to demonstrate their harm reduction benefits. For example, Clive Bates, former Director of the United Kingdom's Action on Smoking and Health, has made the following comments:

> The report places very substantial evidential requirement on those seeking to bring PREPs to the market with a health related claim. The easiest approach for the public health and regulatory community is to demand near complete certainty before approving the marketing of any PREPs. At first sight this appears prudent, but it is actually a *transfer* of risk from the

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[11] *Id*. at p. 2.
[12] Id. at. p. 434.

> regulator to the smoker. With insurmountable evidential hurdles in place, the regulator may sleep easy in a cocoon of professional skepticism.[13]

The IOM Report's focus on the need for further research and demonstration of harm reduction benefits may be understandable in the context of new or novel tobacco products or so-called "safer" cigarettes. When it comes to smokeless tobacco, however, there is considerable agreement in the scientific community that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking.

As Professor Lynn Kozlowski, Head of the Pennsylvania State University Department of Biobehavioral Health, has stated in a commentary published last year in the journal *Nicotine and Tobacco Research*:

> The failure of governments to establish any effective regulation of tobacco products can be seen as arguably the greatest failure of public health policy for the past 100 years. I have recently been in a meeting with several distinguished scientists and opinion leaders interested in smoking-related public policy and regulation. The majority of these individuals expressed an unwillingness to express any public opinion about would-be harm reduction products for tobacco, until such time as proper regulatory/evaluation systems were in place to unequivocally judge the degree of harm reduction afforded by the products as used by society. (This might be viewed as in keeping with the position of the Institute of Medicine report.) Clearly the best of all possible research has not yet been done on snus or medicinal nicotine, but, equally clearly, it is wrong to assume that we lack practical scientific bases for estimating that there will be harm reduction to individual smokers from these products. *Though it is important to attain proper regulation over tobacco and harm reduction products, this goal is logically and ethically independent of the need to provide smokers today with what information we do have about the risks of various products*. (Emphasis supplied).[14]

C. There is General Agreement in the Scientific Community Regarding the Comparative Health Risks of Cigarette Smoking and Smokeless Tobacco Use

[13] Bates C. Clearing the smoke or muddying the water? (Editorial) *Tobacco Control* 2001; **10**: 87-88.

[14] Kozlowski LT. Harm reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options. *Nicotine and Tobacco Res* 2002; **4 Suppl 2**: 55-60 at p. 58.

USSTC's February 5, 2002 Request to the Federal Trade Commission ("FTC") for an advisory opinion[15], which is discussed below, contains excerpts from 50 scientific publications, many of which were peer-reviewed, that assert or support the proposition that the use of smokeless tobacco involves significantly less risk of adverse health effects than cigarette smoking. Additional scientific information and publications that became available subsequent to February 5, 2002 is reviewed in USSTC's May 9, 2003 submission to the FTC, which is also discussed below. Two of the publications referenced in that supplemental submission reflect the generally held view in the public health community regarding the comparative health risks of cigarette smoking and smokeless tobacco use. Those publications can be expected to have a significant impact on the tobacco harm reduction debate, and therefore merit some discussion.

i. Royal College of Physicians Report

In December 2002, the Royal College of Physicians ("RCP") issued a landmark report entitled *Protecting Smokers, Saving Lives*,[16] which assessed various issues relating to future tobacco regulation in the United Kingdom. The RCP is England's oldest medical institution; among its main functions is to advise the government, the public and the medical profession on health care issues.

The 2002 RCP Report recognized that tobacco harm reduction must be an essential element of any tobacco regulation program:

> A tobacco and nicotine regulatory authority should have a clear objective:

[15] Throughout this statement reference will be made to USSTC's February 5, 2002 and May 9, 2003 submissions to the Federal Trade Commission and attachments thereto. Those documents and their attachments can be found at: http://www.ftc.gov/os/otherpubliccomments.htm and http://www.ussmokeless.com. Hereafter, documents that are part of these submissions will be indicated as follows: "See Website."

[16] Tobacco Advisory Group of the Royal College of Physicians. *Protecting smokers, saving lives*. Royal College of Physicians of London, 2002. See Website.

> *…to reduce the overall burden of tobacco-related disease by contributing to a reduction in smoking prevalence and by regulating to reduce the harm caused to continuing nicotine users."* (Original emphasis)[17]

The 2002 RCP Report also recognized that smokeless tobacco would be a key component of any tobacco harm reduction strategy:

> Smokeless Tobacco:
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> As a way of using nicotine, the consumption of non-combustible tobacco is of the order of 10-1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community.[18]

The issuance of the RCP's 2002 Report is not the first time that the RCP has led the way on tobacco and health issues. In March 1962, the RCP issued a report on smoking and health which concluded that cigarette smoking caused lung cancer. Shortly after the issuance of that report, the U.S. Surgeon General, Dr. Luther L. Terry, established the Surgeon General's Advisory Committee on Smoking and Health to produce a similar report for the United States. That report was released in January 1964 and is generally referred to as the 1964 Surgeon General's Report. Its conclusions were similar to those of the 1962 RCP Report.

ii. White Paper on European Union Smokeless Tobacco Policy

In February 2003, a group of tobacco and health researchers and public health advocates from the United Kingdom, Sweden and Austria published a white paper entitled *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public*

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[17] Id. at p. 24.
[18] *Id*. at p. 5

health.[19] The authors recommend that the current European Union ban of smokeless tobacco be replaced with a regulatory program based on the recognition that smokeless tobacco is substantially less harmful than cigarette smoking and could play a significant role in tobacco harm reduction. The group summarized the "public health case" favoring smokeless tobacco as follows:

> We believe that the partial ban applied to *some* forms of smokeless tobacco in the European Union should be replaced by regulation of the toxicity of *all* smokeless tobacco. We hold this view for public health reasons: smokeless tobacco is substantially less harmful than smoking and evidence from Sweden suggests it is used as a substitute for smoking and for smoking cessation. To the extent there is a 'gateway' it appears not to lead to smoking, but away from it and is an important reason why Sweden has the lowest rates of tobacco-related disease in Europe. We think it is wrong to deny other Europeans this option for risk-reduction and that the current ban violates rights of smokers to control their own risks. For smokers that are addicted to nicotine and cannot or will not stop, it is important that they can take advantage of much less hazardous forms of nicotine and tobacco – the alternative being to 'quit or die' … and many die. (Original emphasis)[20]

Among other points made in the white paper are the following:

> [F]or oral tobacco to play a role in harm reduction it is not necessary to show that it does not cause cancer – it just needs to be substantially less hazardous than smoking. Even allowing for cautious assumptions about the health impact, snus – and other oral tobaccos – *are a very substantially less dangerous way to use tobacco than cigarettes.* Smokeless tobaccos are not associated with major lung diseases, including COPD and lung cancer, which account for more than half of smoking-related deaths in Europe. If there is a CVD risk, which is not yet clear, it appears to be a substantially lower CVD risk than for smoking. Smokeless tobacco also produces no environmental tobacco smoke (ETS) and therefore eliminates an important source of disease in non-smokers and children. These are very substantial benefits in reduced risk to anyone that switches from smoking to smokeless tobacco and we believe the public health community has a moral obligation to explore this strategy. It is likewise

[19] Bates C, Fagerstrom K, Jarvis M, Kunze M, McNeill A, Ramstrom L. *European Union policy on smokeless tobacco. A statement in favour of evidence-based regulation for public health.* February 2003. See Website.
[20] *Id*. at p. 2.

> ethically wrong to actively *deny* users the option to reduce their risk in this way.[21]
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> * * *
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> The risk to the user arising from use of a smokeless tobacco product varies by product and is to some extent uncertain – notably in the area of heart disease (though at *worst* the heart disease impact appears to be substantially less than smoking). However, we are confident that the evidence base suggests that it is reasonable to formulate the overall relative risk as follows: *on average Scandinavian or American smokeless tobaccos are at least 90% less hazardous than cigarette smoking.* In a spectrum of risk, snus is *much* closer to NRT [nicotine replacement therapy] than it is to cigarette smoking. (Original emphasis)[22]

D. Individual Risk Versus Population Risk

One concern raised by some in the public health community with respect to "reduced risk" tobacco products is that, while a product might reduce the health risk to an individual, the aggregate public health impact on the population might be negative. Thus, for example, it is argued that if a "safer" cigarette reduced the health risks associated with cigarette smoking by 10 percent, but resulted in a 20 percent increase in cigarette use (either through new smokers or by causing some smokers who otherwise would have quit to continue smoking), the aggregate public health impact would be negative. Professor Kenneth E. Warner of the University of Michigan gives the following example:

> [C]onsider the implications of Star Enterprise's advertising that its new cigarette, Advance, yields fewer nitrosamines than conventional cigarettes. Informed that most cigarette smoke contains nitrosamines and that nitrosamines are carcinogenic, would smokers preparing to quit flock to the new cigarette instead, believing that it would greatly reduce their risk of smoking-induced lung cancer? The net health consequences are unclear: for those smokers who would have continued smoking anyway, switching to Advance might well reduce risk. For smokers who would have quit, or former smokers induced to start smoking again

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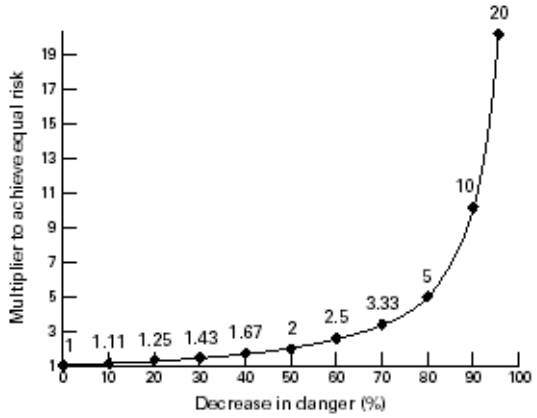
[21] *Id*. at p. 3.
[22] *Id*. at pp. 3-4.

> by the availability of this purportedly 'safer' product, the active marketing of a low-nitrosamine cigarette clearly would *increase* risk. The net impact would depend on the unpredictable balance between such effects.[23]

Professor Kozlowski has developed a "risk/use equilibrium" chart[24] to assess the issue of individual risk reduction versus aggregate population impact. The chart compares the "decrease in danger (%)" displayed on the horizontal axis to the "multiplier to achieve equal risk" on the vertical axis.



According to Professor Kozlowski's analysis, a tobacco product that reduces risk by only 10 percent raises a difficult public health issue because an 11 percent increase in use of the product would offset the risk reduction in the population as a whole, and an increase in excess of 11 percent would result in a negative public health impact on the population as a whole. On the other hand, a tobacco product that results in a reduced risk in excess of 90 percent presents a relatively easy public health issue since the increase in usage necessary to offset the reduction in risk is so substantial – more that 1,000 percent – that it is highly unlikely to occur.

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[23] Warner KE. Reducing harm to smokers: Methods, their effectiveness and the role of policy. In: Regulating Tobacco. Rabin RL, Sugarman SD (eds.) Oxford University Press, Oxford. 2001. Chapter 5, at pp. 133-134.

[24] Kozlowski L, Strasser AA, Giovino GA, Erickson PA, Terza JV. Applying the risk/use equilibrium: use medicinal nicotine now for harm reduction. (Editorial). *Tobacco Control* 2001; **10**: 201-203.

Given the predominant view in the public health community that the risk of adverse health effects associated with smokeless tobacco products is slight compared to that of cigarette smoking, researchers believe it is highly unlikely the public health benefit of cigarette smokers switching to smokeless tobacco would ever be offset by increased usage of smokeless tobacco.

Professor Kozlowski expressed his agreement with this conclusion in a recent publication entitled *Harm Reduction, public health, and human rights: Smokers have a right to be informed of significant harm reduction options*, in which he applied his "risk/use equilibrium" analysis to smokeless tobacco:

> When risks from a product are relatively small, the level of increased use needed to maintain a public health equilibrium (no changes in population-level problems) becomes very high (Kozlowski, Strasser, Giovino, et al., 2001). . . . For a product like snus, if the risk is even 1% that of cigarettes, use would have to increase 100 times to equal the problems from cigarettes. If the risk from snus were as much as 5% that of cigarettes, use would still have to increase an unlikely 20 times for the public health problems to equal those from cigarettes.[25]

E. The Swedish Experience

Proponents of encouraging "inveterate" cigarette smokers to switch to smokeless tobacco products point to the history of cigarette smoking and smokeless tobacco use in Sweden as support for their view. Swedish males have the highest rate of smokeless tobacco use and the lowest rate of cigarette smoking of any Western country, and the daily use of smokeless tobacco by Swedish males now exceeds that of cigarettes (18.2 percent daily smokeless tobacco users versus 17.1 percent daily cigarette smokers).[26] The following chart illustrates the changing pattern of tobacco use in Sweden during most of the past century, including the fact that

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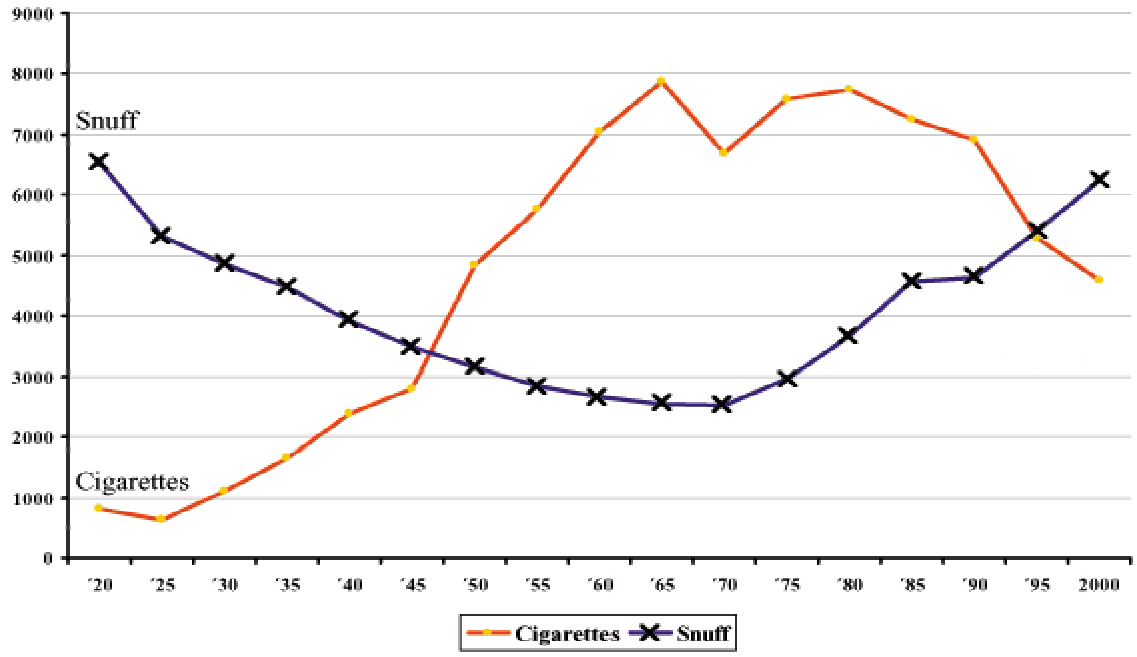
[25] Kozlowski LT (2002) at p. 58.

[26] Henningfield JE, Fagerström KO. Swedish Match Company, Swedish snus and public health: a harm reduction experiment in progress? *Tobacco Control* 2001; **10**: 253-257, at p. 254.

smokeless tobacco use has overtaken cigarette smoking in recent years for the first time since World War II.[27]



Tobacco and health researchers have linked Sweden's low rate of "tobacco-related mortality" to its high prevalence of smokeless tobacco use and low prevalence of cigarette smoking:

> Sweden, with a long tradition of smokeless tobacco use (16% of adult males use smokeless tobacco daily) and the highest penetration of NRT [nicotine replacement therapy] use, is the only European country that has reached (19%) the World Health Organization's target of 20% smokers in the adult population by the year 2000; about 35% of all nicotine consumed comes from nonsmoked deliver[y] forms. The tobacco-related mortality in Sweden is by far lower than in any other European or North American country, although nicotine consumption may not be lower than in other countries.[28]

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[27] Adapted from Swedish Match's Third Quarter Results, October 23, 2001, as posted on Company's web site. The figures cited reflect reported taxable shipments of snuff and cigarettes, measured in tons.

[28] Balfour DJK, Fagerström KO. Pharmacology of nicotine and its therapeutic use in smoking cessation and neurodegenerative disorders. *Pharmacol Ther* 1996; **72**: 51-81, at p. 71.

In 2001, a *New Scientist* article summarized the Swedish experience in the context of tobacco harm reduction:

> [S]mokers [in Sweden] aren't faced with the quit-or-die dilemma. Instead of using a nicotine replacement therapy with the aim of quitting both smoking and ultimately nicotine, they can continue using tobacco as a recreational drug, safe in the knowledge that it probably won't kill them. It's all down to a product called 'snus,' a form of moist ground tobacco that you pop between your lip and gum.[29]
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> * * *
>
> The 'Swedish experiment,' as it has come to be known, has inspired some health campaigners to press for a more enlightened approach to the smoking epidemic. It's a concept they call 'harm reduction.' 'If you look at Sweden, we have a living example of the concept in action,' says Clive Bates, director of ASH.[30]

Also of interest is Swedish survey data regarding the use of smokeless tobacco as a smoking cessation aid presented at two scientific conferences in late 2002. At the *3rd International Conference on Smokeless Tobacco: Advancing Science and Protecting Public Health,* held in Stockholm, Sweden in September 2002, Dr. Lars M. Ramström, Director of Stockholm's Institute for Tobacco Studies, reported on a recent nationwide survey of a representative sample 6,700 adults in Sweden sponsored by the Swedish National Institute of Public Health. Dr. Ramström reports the following in the press summary of his presentation:

> "Among males snus is the most commonly used and most effective smoking cessation aid." In support of this conclusion, Dr. Ramström cites survey data indicating that "76% of male Ever Daily Smokers have made at least one attempt to quit smoking. Around 40% of the 'triers' report that at their latest attempt they have used some kind of smoking cessation aid. 36% of these males have used nicotine gum, 20% nicotine patch and 55% have used snus as a smoking cessation aid. No other kind of cessation aid has been used by as much as 10%.[31] The proportion of those

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[29] Wilson C. My friend nicotine. *New Scientist* 2001; **10**: 28-31, at p. 29.
[30] *Id*. at p. 30.
[31] Dr. Ramström noted that the total exceeds 100% because some smokers used more than one aid.

> who have succeeded to quit smoking completely is 50% for gum users, 34% for patch users, 65% for snus users."[32]

At the *4th European Conference of the Society for Research on Nicotine and Tobacco: Improving Knowledge and Treatments of Nicotine Addiction*, held in Santander, Spain in October 2002, Clive Bates made a presentation entitled "Harm Reduction and Smokeless Tobacco." One of the points made was that "snus is an important factor in the low smoking prevalence in Sweden. It is used for cessation and as an alternative to smoking." He cited data from a 2001 survey commissioned by the Swedish Cancer Society reporting that, among 1,000 ex-smokers, 33% used snus as a smoking cessation aid, compared to 17% who used nicotine replacement therapies.[33]

The European Union white paper also points to smokeless tobacco as the explanation for Sweden's low rate of tobacco-related mortality:

> Evidence from Sweden suggests snus plays a positive public health role as a substitute for smoking and as an aid to smoking cessation. It is impossible to be definitive about this, because it is impossible to run a controlled trial on a whole nation.
>
> However, consider the following:
>
> - Sweden has the lowest levels of tobacco-related mortality in the developed world by some distance – approximately half the tobacco related mortality of the rest of the EU.
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> - Sweden has the lowest male smoking prevalence in Europe (16% daily) and low female (c. 22%) prevalence.
>
> - However, it has comparable male *tobacco* prevalence and total consumption to neighbours Norway and Denmark - suggesting the big difference is in the *type* of tobacco used, rather than overall propensity to use tobacco or consume nicotine.

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[32] Ramstrom L. Press summary entitled: Snus as a substitution for smoking – the Swedish Experience. See Website.

[33] Bates C. Presentation: Harm reduction and smokeless tobacco. See Website.

- About half of tobacco in Sweden is now consumed as snus - this share has steadily grown since 1970s.

- 33% of ex-smokers report use of snus - almost twice the number that report use of a pharmaceutical treatment (17%). Among males who have used a single aid to stop daily smoking, and succeeded to do so, some 70% had used snus and some 30% had used some kind of NRT.

Some have raised a question as to whether the Swedish experience is applicable to the United States, asserting that Swedish moist snuff products contain lower levels of so-called tobacco-specific nitrosamines (some of which have been reported to be laboratory carcinogens) than U.S. moist snuff products. For example, Professor Newell Johnson in an article published in 2001 entitled "Tobacco Use and Oral Cancer: A Global Perspective" conceded that "on present evidence, snuff habits as they exist in Scandinavia and probably in the United States carry lower risk of serious health hazards"[34] than cigarette smoking, but also made the following comment:

> In Scandinavia it is clear that local snuff is not a major risk factor: two recent case-control studies of oral cancer cases in Sweden have failed to show an association. This is because Swedish snus is not fermented and contains much lower nitrosamine levels than fermented tobaccos. The view that smokeless tobacco use may be associated with a lower risk of oral cancer in the United States has led to a movement to advocate the practice as a less dangerous alternative to smoking and an aid to nicotine withdrawal in those addicted to smoking.[35]

In fact, there is currently no significant difference in tobacco-specific nitrosamine (TSNA) levels in U.S. moist snuff products compared to Swedish moist snuff. Data reported in

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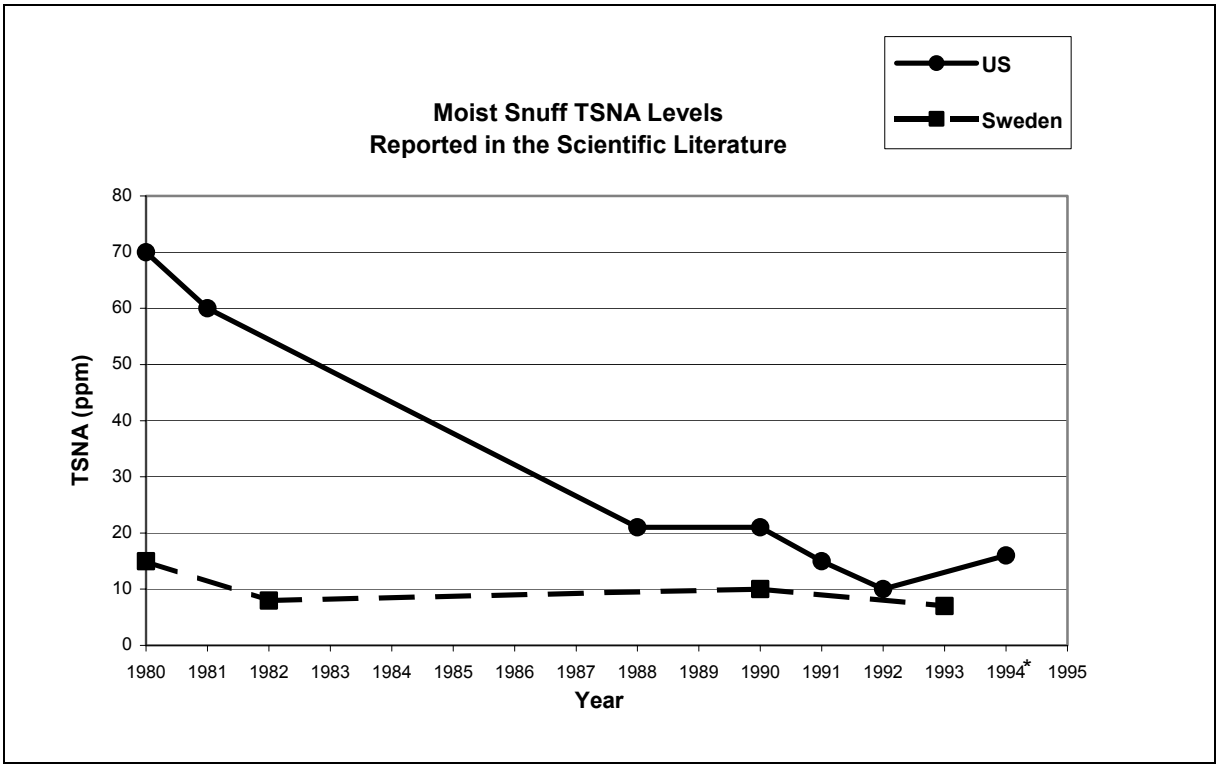
[34] Johnson N. Tobacco use and oral cancer: A global perspective. *J Dent Educ* 2001; **65**: 328–339, at p. 328.
[35] *Id*., at pp. 332-333.

scientific literature by researchers from the American Health Foundation, together with data published by Swedish researchers,[36] show that the average levels of TSNAs in the major U.S. the moist snuff products decreased 77% between 1980 and 1994 (the last time that data for both of these products was reported in the scientific literature), and that currently there is no significant difference between the levels of TSNAs in those products compared to Swedish moist snuff products. A chart depicting this data follows:

[36] Andersson G, Bjornberg G, Curvall M. Oral mucosal changes and nicotine disposition in users of Swedish smokeless tobacco products: A comparative study. *J Oral Pathol Med* 1994; 23: 161-167 (1993 Swedish data); Djordjevic MV, Brunnemann KD, Hoffmann D. The need for regulation of carcinogenic N-Nitrosamines in oral snuff. *Food Chem Toxicol* 1993; 31: 497-501 (1992 U.S. data and all earlier data); Hoffmann D, Djordjevic MV, Fan J, Zang E, Glynn T, Connolly GN. Five leading U.S. commercial brands of moist snuff in 1994: assessment of carcinogenic N-Nitrosamines. *J Natl Cancer Inst* 1995; 87: 1862-1869 (1994 U.S. data).



TSNA =Total of reported levels of NNN, NNK, NAT and NAB on dry weight basis in parts per million

US = Average of reported TSNA levels for leading American moist snuff products which, according to the researchers, "accounted for 84% of the snuff sales on the US market (Maxwell, 1992)," excluding anomalous data for 1986

Sweden = Average of reported TSNA levels for three unidentified Swedish moist snuff products

* No comparable data reported in the scientific literature for any period after 1994

This view is supported by a report issued in 1997 by the Swedish National Board of Health and Welfare, which concluded:

> Recent data suggest that the differences [in TSNA levels reported in American and Swedish moist snuff] have grown smaller, and that it is now questionable to make a sharp distinction between use of American and Swedish moist snuff when assessing risks -- at least where TSNA content is concerned.[37]

F. The Gateway Issue

One argument relied upon by those who oppose the use of smokeless tobacco as a component of a tobacco harm reduction strategy is that smokeless tobacco may be a causal "gateway" to cigarette smoking, that is, smokeless tobacco use may cause consumers to later take up cigarette smoking.

The authors of the EU white paper reject the notion of a causal "gateway" from smokeless tobacco to cigarette smoking based upon their assessment of empirical data from Sweden and their analysis of the studies relied upon by those who argue that there is a "causal" gateway effect. Indeed, the authors of the EU white paper conclude that the Swedish data suggest that smokeless tobacco prevents rather than promotes cigarette smoking:

> **Gateway effects.** There is concern that smokeless tobacco will function as a lead-in to smoking for people that would not otherwise smoke. Such 'gateway effects' are always contentious, and they are hard to demonstrate for the simple reason that we do not know what smokeless users would have done in the absence of smokeless tobacco - they may have simply moved straight to smoking. Gateways can act in the opposite direction too – they can be 'exits' rather than 'entrances'. Smokers may move to smokeless tobacco or use smokeless tobacco to quit, where they would otherwise have continued to smoke. Starters on smokeless tobacco may continue as smokeless users but otherwise have started with cigarettes, so that smokeless tobacco is a diversion from smoking. In both the US and

[37] Ahlbom A, Olsson UA, Pershagen G. Health hazards of moist snuff. *SoS Report* 1997; 11:3-29, at p. 7.

Sweden, most smokeless tobacco use *cannot* be a gateway to smoking, either because smokeless users never started smoking or because they started smoking first. For the minority who started using smokeless before cigarettes they may or may not have had their smoking caused by smokeless use.

Exit or entrance gateway? Understanding the order in which tobacco users take up different products is an important and necessary factor in establishing a gateway effect and whether the gateway is an exit from or entrance to smoking, but it is not in itself sufficient to establish a gateway from smokeless to cigarettes. The basic problem is that it is difficult to know whether those that start with smokeless tobacco would otherwise have started on cigarettes in the absence of smokeless tobacco. The data from Sweden suggest that the gateway is more likely to be an 'exit' from smoking than an 'entrance'. Among Swedish males with a primary use of snus no more than 20% ever started smoking, while 45% of other males did become smokers. In addition to this compelling evidence from the pattern of transitions, Sweden has the lowest rate of male smoking in Europe, combined with high levels of snus use. There is no other credible explanation for such low male smoking prevalence than the displacement and cessation of smoking through smokeless tobacco use. In total therefore, the Swedish data suggest that uptake of snus use prevents rather than promotes smoking and therefore contributes a net public health benefit. There have been studies in the United States that claim to show a gateway effect from smokeless tobacco use to smoking for a minority of smokeless users. However, these studies or related commentary have generally drawn causal inferences based on observation of transitions between often poorly defined categories of tobacco use, and sometimes from groups that are unrepresentative of the general population, such as the military. Psychosocial predictors of smoking initiation (school performance, parental smoking, risk taking etc.) can be used to assess which smokeless tobacco users might otherwise have been smokers. When these confounding factors are taken into account, the data do not show that initial smokeless tobacco use adds to the propensity to become a smoker.

Additional data from Sweden contradicting the theory of a causal "gateway" from smokeless tobacco to cigarette smoking was recently published by Rodu et al. in a paper entitled *Evolving patterns of tobacco use in northern Sweden*.[38] The researchers report on their analysis of data from a prospective follow-up study of approximately 3,400 men and women in northern

[38] Rodu B, Stegmayr B, Nasic S, Cole P, Asplund K. Evolving patterns of tobacco use in northern Sweden. *J Intern Med* 2003; **253**: 660-665.

Sweden, and describe the evolving patterns of tobacco use in this population over the period 1986 to 1999. While the researchers conclude that "the use of snus played a major role in the decline of smoking rates amongst men in northern Sweden,"[39] some of their data is of particular relevance to the "gateway" issue. They report that among men who used moist snuff but had never smoked at the beginning of the study, not a single person switched to cigarette smoking during the follow-up period of 5 to 13 years, and only 1 percent of these men used both moist snuff and cigarettes during the follow-up period.

G. Cigarette Smokers' Misperception that Smokeless Tobacco and Cigarettes Involve Equal Health Risks and Their Right to Accurate Information

At the November 2001 meeting of the National Conference on Tobacco or Health in New Orleans, Louisiana, Dr. K. Michael Cummings of New York's Roswell Park Cancer Institute, and his colleagues, presented results of a survey of a nationally representative sample of over 1,000 adult cigarette smokers regarding their beliefs about tobacco products. Of particular interest was the fact that 82% of adult cigarette smokers responded that they believed smokeless tobacco was just as likely to cause cancer as smoking cigarettes.[40]

Given these survey results, it was not surprising that in a 2002 publication, Dr. Cummings made the following comments regarding the comparative health risks of smokeless tobacco and cigarettes, and the need to provide adult cigarette smokers sufficient information to permit them to make informed choices regarding the tobacco products they choose to use:

> Competition to produce more consumer-acceptable medicinal nicotine products would be helped by educating consumers about what factors in

[39] *Id*. at p. 660.

[40] Presentation by Dr. K. Michael Cummings at the National Conference on Tobacco or Health in November 2001.

> tobacco products really contribute to disease risk. Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes. Yet if all nicotine products were put on a risk continuum the actual difference between smokeless and nicotine medications would be seen as fairly minor compared to the difference in disease risk between smoked and smokeless products (Stratton *et al.* 2001). *Until smokers are given enough information to allow them to choose products because of lower health risks, then the status quo will remain*. Capitalism, and not governmental regulation, has the greatest potential to alter the world-wide epidemic of tobacco-related disease. (Emphasis supplied)[41]

Professor Kozlowski has also commented recently concerning the urgent need to provide cigarette smokers with information regarding risk reduction options and their right to receive such information:

> Cigarettes kill about half of those who smoke them . . . It is urgent to inform smokers about options they have to reduce risk. This needs to be done in ways that inform smokers as fully as possible that never starting and complete quitting as soon as possible are the best choices to promote health, while also indicating that snus or medicinal nicotine (the latter more than the former) would be preferable to continued smoking. Also, complete substitution of these products should be encouraged over mixing them with continued smoking. The harm reduction message will be complex. There will be many ways to give it. Some will misinterpret even the most artfully framed message. Notwithstanding, public health policy in this instance lacks compelling justification to override the human rights of the individual. Individuals have the right to such health relevant information.[42]

H. USSTC's Request for FTC Guidance

On February 5, 2002, USSTC filed a request with the FTC seeking issuance of an advisory opinion regarding the acceptability of communicating in advertising that smokeless tobacco products are considered to be a significantly reduced risk alternative as compared to cigarette smoking (See Website). USSTC noted in its request that issuance of an advisory

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[41] Cummings KM. Can capitalism advance the goals of tobacco control? Addiction 2002; **97**: 957-958 at p. 957.
[42] Kozlowski LT. (2002) at p. 59.

opinion by the FTC would address an issue of significant public interest to adult tobacco consumers, USSTC, and other smokeless tobacco manufacturers. USSTC explained the rationale behind its request as follows:

> USSTC requests that the Commission issue an advisory opinion supporting the use of statements in advertising that provide the public with truthful and substantiated information about the harm reduction that a growing number of public health advocates believe can result from switching from cigarettes to smokeless tobacco products. The benefits of making such information available to consumers would be twofold: it would provide ready access to scientific opinion that otherwise would be difficult or costly to obtain, and it would help adult consumers make better educated choices about the tobacco products they use. As the federal agency with authority over tobacco advertising, the FTC should act affirmatively to provide guidance in this area.
>
> USSTC believes that the types of information it proposes to communicate in advertising are truthful, non-misleading and substantiated. At the same time, USSTC recognizes that cross-category (*i.e.*, smokeless tobacco advertisements directed at adult smokers) comparative advertising of reduced risk tobacco products raises issues which currently are the subject of ongoing public health debate. Providing USSTC with an advisory opinion would inform USSTC and other smokeless tobacco manufacturers of the criteria the FTC will apply when considering such statements. At a minimum, FTC consideration of these issues would advance the public debate on the issue of tobacco harm reduction, and increase the amount of information available to the public regarding reduced risk alternatives to cigarette smoking. Indeed, as part of its consideration of this request, the FTC may wish to hold a public workshop or similar forum to facilitate a full exchange of views on the issues involved.

USSTC's request made clear that any statement USSTC made would be truthful and non-deceptive, and gave an example of the type of statement contemplated:

> USSTC proposes to disseminate advertisements with the following or similar statements:
>
> > *The Surgeon General in 1986 concluded that smokeless tobacco "is not a safe substitute for smoking cigarettes." While not asserting that smokeless tobacco is "safe," many researchers in the public health community have expressed the opinion that the use of smokeless tobacco involves*

> *significantly less risk of adverse health effects than smoking cigarettes. For those smokers who do not quit, a growing number of researchers advocate switching to smokeless tobacco products*.

Following the submission of its request to the FTC, USSTC representatives met with FTC staff representatives on May 21, 2002 in order to present an overview of various issues relating to its request, as well as to answer any questions that might be raised by the FTC staff. Following the presentation and discussion, USSTC provided to the FTC staff additional information and documentation responsive to their requests. A similar meeting was held with representatives of Department of Health and Human Services public health agencies on May 30, 2002. Copies of the presentation materials relating to these meetings are annexed as Attachments B and C.

In the spring and summer of 2002, smokeless tobacco and tobacco harm reduction was the topic of discussion and debate at various scientific conferences and public policy forums in the United States and abroad. On May 16, the subject was discussed at a scientific conference in London entitled *Harm Reduction, Smoking and Smokeless Tobacco*; on May 29, the issue was the subject of a forum entitled *Marketing Highly Regulated Products* at Northwestern University in Chicago; on June 20 through 22, the issue was discussed at the *Third European Conference on Tobacco or Health* in Warsaw, Poland; on June 26, the issue was debated at a seminar sponsored by the American Council on Science and Health in New York City; and on July 16, the issue was the subject of debate at the CATO Institute in Washington, DC.

In the summer of 2002, USSTC became aware of the scheduling of two very important scientific conferences that would include a public debate directly relevant to USSTC's request. On September 22 through 25, 2002, the Centers for Disease Control, the National Cancer

Institute, and the Stockholm Center of Public Health, Center For Tobacco Prevention, would sponsor the *3rd International Conference on Smokeless Tobacco: Advancing Science & Protecting Public Health*, in Stockholm, Sweden. The conference would bring together leading experts on smokeless tobacco, and feature a session on tobacco harm reduction. Similarly, the *4th European Conference of the Society for Research on Nicotine and Tobacco* was to be held on October 3 through 5, 2002, in Santander, Spain. This conference would also include discussion and presentations of research findings on current scientific issues relating to smokeless tobacco, including harm reduction. In view of the pendency of these scientific conferences, on August 12, 2002, USSTC temporarily withdrew its request for an advisory opinion so that it would have the opportunity to provide for the FTC's consideration significant new information expected to be presented at these conferences.

On May 9, 2003, USSTC submitted to the FTC information regarding smokeless tobacco as a reduced risk alternative to cigarette smoking that had been presented or published subsequent to the August 2002 temporary withdrawal of its request for FTC guidance. As expected, the Stockholm and Santander conferences produced important new information relevant to USSTC's request. More significantly, however, two publications had appeared in late 2002 or early 2003 that will have a major impact on the public debate regarding smokeless tobacco in the context of tobacco harm reduction. Those publications, discussed above, are a report from London's Royal College of Physicians and a white paper prepared by a group of European tobacco and health researchers and public health advocates. In addition, several other scientific publications or documents had appeared that were relevant to USSTC's request for FTC guidance.

Significant new information from the above-referenced scientific conferences and publications was reviewed in USSTC's May 9, 2003 filing, submitted together with copies of the referenced materials (See Website).

USSTC suggested in its submission to the FTC that the Commission may wish to consider holding a workshop or other forum to address the appropriateness of conveying tobacco harm reduction information as part of smokeless tobacco advertising. USSTC continues to believe that such a workshop would afford all of the participants in this public health debate an opportunity to present their views in a constructive and productive manner. It might also help form a consensus as to how we move forward on this important public health issue and could provide guidelines to ensure that any comparative risk communication is directed at adult smokers to avoid any unintended consequences.

III. Conclusion

Some tobacco control activists have taken the position that USSTC should be prevented from communicating to adult cigarette smokers the prevailing view in the scientific community regarding the comparative health risks of tobacco products. Interestingly, they also believe that neither the federal government nor the public health community has any responsibility to undertake that task.

On the other hand, some in the public health community believe that communication of that vital information could have a significant positive impact on the lives of adult cigarette smokers. Indeed, some in the public health community believe that USSTC must confront the question of whether it has a responsibility to step forward and communicate this critical

information to adult cigarette smokers in light of the vacuum created by the federal government and the tobacco control activists.